UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,128	08/29/2005	Bronislava Gedulin	54061.8101.US00	7370

44638 7590 03/05/2008

Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,128	GEDULIN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *7 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 6, 8-12, and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 12/19/200704/20/2007 has been entered. Claims 1-3, 5-12, and 14-21 are pending. Claims 1-3, 5, 6, 8-12, and 14 are under consideration.

Withdrawn Objections and/or Rejections

The objection to claim 1 for minor informality is withdrawn in view of amended claim 1.

Information Disclosure Statement

The information disclosure statement filed on 12/19/2007 is considered by the Examiner and a signed copy has been attached to the office action.

Claim Rejections Under 35 U.S.C.§112, 1st Paragraph (Written Description)

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). The rejection of claims 1-3, 5, 6, and 8-12 under 35 U.S.C. 112, first paragraph for written description is maintained for the reasons set forth in the previous office action mailed on 09/05/2007.

Beginning at the 2nd paragraph of page 6 of Applicants' response filed on 12/19/2007, Applicants review the legal standard for written description, with which the examiner takes no issue.

At page 6, Applicants argue that the art at the time of the effective filing date of the instant application contained ample structural and functional information concerning PYY and PYY analogs as recited in the instant claims. Citing a number of references, Applicants argue that structural determinants unique to numerous PYY and PYY analogs and correlations of such determinants to PYY and PYY agonist function were taught in the art.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while teaching PYY and PYY[3-36] that may be used in treating an intestinal damage, the cited references do not teach the broad genus of PYY agonists encompassed in the instant claims. The cited references do not teach the structural determinant, "an active fragment of PYY". If Applicants believe that the prior art teaches representative species of the genus of agonists in the context of the claimed methods, they are requested to clearly point them out; if Applicants believe that the prior art teaches the structural feature of the encompassed genus of PYY agonist or the active fragment of PYY, they are also requested to clearly state what it is and where it is taught.

At page 8, the 3rd paragraph, Applicants argue that human PYY[3-36] of SEQ ID NO: 3, which displays 94% identity with respect to rat PYY, elicits the disclosed effects when administered to rat constitutes a de facto showing that a PYY agonist, as recited in the claims, is efficacious order to practice the instantly claimed methods.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while providing an adequate description of a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY or a PYY agonist, PYY[-3-36], to a human to treat the intestinal damage, the specification does not provide adequate description for a method comprising administration of a genus of structurally undefined PYY agonists for the reasons set forth above and in the previous office action mailed on 09/05/2007.

At page 8, the 4th paragraph, Applicants argue that the scope of the genus of PYY and PYY agonists is viewed in the context of the claimed methods. Applicants argue that the claims are not drawn to a novel genus of compound, but rather to novel use of a known set of compounds.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the requirement for written description under 35 U.S.C. 112, first paragraph is applicable to a method of using a genus of compounds. A genus of compounds to be used in a method needs to be adequately described. If a genus of compounds does not

meet the requirement for written description, a method of using such a genus of compound does not meet the requirement for written description.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of PYY agonists and thus methods of using the genus of PYY agonists.

Claim Rejections Under 35 U.S.C. §102 (b)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii). The rejection of claims 1, 2, 5, and 10-12, are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) is maintained for the reasons set forth in the previous office action mailed on 09/05/2007.

Applicants argue that the cited prior art does not disclose each and every element of the present claims, and therefore, does not anticipate the instant claims. Applicants argue that Balasubramaniam does not teach or suggest a method of treating intestinal damage, or a method of treating intestinal damage associated with any of the conditions. Applicants argue that the reference fails to provide any nexus between the

alleged teaching of treating gastrointestinal disorders and treating the damage caused by such disorders per se.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the instant claims are drawn to a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a human to treat the intestinal damage, whereas Balasubramaniam teaches treating any gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease, with PYY (column 7). Moreover, Balasubramaniam teaches that PYY inhibits gut motility and blood flow, attenuates basal and secretagogue-induced intestinal secretion in humans. Balasubramaniam further teaches that PYY plays a physiological role in regulating intestinal secretion and absorption, serving as natural inhibitors of diarrhea (column 1, lines 35-54; column 6, lines 43-67). Thus, Balasubramaniam teaches administering PYY to a subject to treat intestinal damages associated with these diseases.

Claim Rejections Under 35 U.S.C.§103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the

prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). The rejection of claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) and further in view of Dumont et al. (Brain Res. Mol. Brain Res. 26: 320-324, 1994) is maintained for the reasons set forth in the previous office action mailed on 09/05/2007.

Applicants argue that Balasubramaniam fail to teach a method of treating intestinal damage that might result from a gastrointestinal disorder, per se, comprising administering a pharmaceutically active of PYY or a PYY agonist polypeptide as instantly claimed. While Dumont et al. may teach a PYY agonist, PYY[3-36], Dumont et al. fail to cure the deficiencies of Balasubramaniam. Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons set forth above.

(iii). The rejection of claims 1-3, 5, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Salhy et al. (Peptides 23:397-402, February 2002) is maintained for the reasons set forth in the previous office action mailed on 09/05/2007.

Applicants argue that El-Salhy et al. fail to teach or suggest any nexus between "a decrease in PYY levels in patients with gastrointestinal disorders, including inflammatory diseases" and a therapeutic benefit that might be achieved by administering PYY or PYY agonist to such patients, and certainly does not teach that

such a benefit comprises the treating intestinal damage that is associated with such disorders. Applicants argue that whereas the reference allegedly hypothesizes that "changes in PYY in gastrointestinal disorders could be beneficial in clinical practice and in cases where PYY increase is desirable, diet that increases PYY synthesis and release can be followed, or a receptor agonist can be utilized", such hypothesis fails to teach which particular changes (e.g., an increase, a decrease, etc.) would be beneficial in which particular "clinical practice", or how such particular changes might be exploited such that a therapy for such a "clinical practice" is achieved. Applicants further submit that the reference of El-Salhy et al. advertises the ambiguous, contradictory, and inconclusive nature of its alleged "teachings" throughout.

Applicants' argument has been fully considered, but is not deemed to be persuasive El-Salhy et al. teach a decreased level of PYY in human patients with gastrointestinal disorders, including inflammatory bowel diseases (examples are Crohn's colitis and ulcerative colities; pages 398-399). El-Salhy et al. also teach that the changes in PYY in gastrointestinal disorders could be beneficial in clinical practice and that in cases where PYY increase is desirable, diet that increases PYY synthesis and release can be followed, or a receptor agonist can be utilized (Abstract; page 401). El-Salhy et al. further teach that infusion of PYY in dogs increases colonic absorption of water, Na and Cl ions and PYY or its analogue can be of use as clinical agents in intestinal malabsorption disorders or after bowel resection (page 401). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

administer PYY to a subject or a human patient after bowel resection or to treat a gastrointestinal disorders, including inflammatory bowel diseases (such as ulcerative colities) with a reasonable expectation of success. The administering PYY to a subject or a human patient with a gastrointestinal disorder would necessarily treat damage caused by the gastrointestinal disorder.

Applicants argue that the dogs in the study did not have an intestinal damage associated with an inflammatory bowel disease. Applicants submit that this alleged teaching simply fails to offer any nexus between water and nutrient absorption in healthy dogs and a method of treating any disorder or condition whatsoever.

Applicants' argument has been fully considered, but is not deemed to be persuasive because El-Salhy et al. clearly teach that infusion of PYY in dogs increases colonic absorption of water, Na and Cl ions and PYY or its analogue can be of use as clinical agents in intestinal malabsorption disorders or after bowel resection (page 401), whereas intestinal malabsorption disorders or bowel resection are an intestinal damage.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
February 24, 2008